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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/068,292	02/06/2002	Toshikazu Hirota	789 076	9651

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EXAMINER	
LAM, ANN Y	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 08/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/068,292	HIROTA ET AL.	
	Examiner	Art Unit	
	Ann Y. Lam	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7,8,11-32 and 58-63* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7,8,11-32 and 58-63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *May 11, 2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 7, 8, 11, 14, 16-19, 21-22, 26-32 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brennan, 5,474,796.

Brennan discloses the invention substantially as claimed. More specifically, as to claims 7 and 8, Brennan discloses a method for producing a biochip comprising the steps of:

providing a substantially planar based plate (col. 2, line 29, and fig. 3);

supplying onto the upper surface of said base plate, a plurality of solution samples each containing a capture (col. 7, lines 53-55, and fig. 3) used to specifically react with a specimen in order to obtain information on a structure or a function of said specimen (col. 3, lines 11-12);

supplying a solution containing no capture separately from and in the same location as each of said solution samples (col. 7, lines 46-47)

wherein one of said solution sample and said solution is supplied onto the other one of said solution sample and said solution while said other one of said solution sample and said solution is in solution form (col. 7, lines 46-56). (The Office notes that

the solution sample containing capture is disclosed as being in droplets, see column 7, in 53, and thus is in solution form. The solution containing no capture is also in solution form because it is disclosed as having a surface tension, see column 7, lines 46-47.)

While Brennan discloses supplying a solution containing no capture in the same location as each of the solution samples, Brennan does not specifically disclose that the solution containing no capture is supplied in accordance with an ink-jet system. (Brennan discloses using printing to apply oligonucleotides—see column 8, lines 25 and 44-46, which are equivalent to Applicant's solution samples. However, Brennan does not specifically disclose that the silane reagent, e.g., hydroxyalkylsiloxane on page 7, line 51, or aminoalkylsilane on column 2, lines 41-42, are deposited by an ink-jet system. The "chemical reactants" disclosed in column 2, line 13, which are deposited by a piezoelectric pump, i.e., ink-jet system, refer to reactants that are deposited on a binding site, i.e., the site with the silane reagent. Thus, the chemical reactants are not specifically disclosed by Brennan to be depositing the silane reagent.)

However, Sluka et al. teach that reaction partners can be applied to respective spots by ink-jet printing (col. 11, lines 13-15) thereby forming a pattern of spots (col. 7, lines 37-38) which enables a concurrent qualitative or quantitative determination of a multitude of analytes in a sample or of one analyte in different samples in a small space and requires only very small amounts of reagent for analytical purposes (col. 8, lines 52-59). It would have been obvious to one of ordinary skill in the art at the time the invention was made to apply the Brennan silane reagent, (which is equivalent to Applicant's solution containing no capture) using ink-jet printing as taught by Sluka et al.

because Sluka et al. teach that reaction partners, such as the oligonucleotides and the silane reagent, can be applied to respective spots by ink-jet printing which allows for forming a pattern of spots as would be desirable for enabling a concurrent qualitative or quantitative determination of analytes in a sample or of one analyte in different samples in a small space.

As to claim 11, the solution containing no capture (col. 5, lines 26-30 and col. 7, lines 46-56, and fig. 3) is an immobilization solution for immobilizing said captures onto said base plate or an immobilization-reinforcing solution for reinforcing immobilization of said captures onto said base plate.

As to claim 14, the immobilization solution or immobilization-reinforcing solution is supplied onto said base plate, and then said solution sample is supplied to parts to which said immobilization solution or immobilization-reinforcing solution has been supplied (col. 6, lines 8-17 and figure 3.)

As to claim 16, the captures are nucleic acids (col. 5, lines 1-9).

As to claim 17, the nucleic acid is DNA or fragment thereof (col. 5, lines 1-9.)

As to claim 18, the captures are proteins (col. 3, lines 23-25.)

As to claim 19, the protein is antibody (col. 2, lines 22-26.)

As to claims 21, the immobilization solution is a silane coupling agent (col. 5, lines 26-30 and col. 7, lines 46-56.)

As to claim 22, the immobilization solution includes a chemical substance for chemically modifying a base plate surface (col. 7, lines 46-48), and a functional group introduced into said base plate surface, and a functional group introduced by modifying

said capture are subjected to a chemical reaction to immobilize said capture onto said base plate by means of covalent bond (col. 7, lines 46-55.)

As to Claims 26-29, since the immobilization-reinforcing solution was recited in the alternative (see claim 11), these claims are anticipated by the disclosure of the immobilization solution (col. 7, lines 46-55.)

As to claim 30, the method further comprises preparing a jig (i.e., "mechanical stage" in col. 8, lines 57-58) to which a plurality of said base plates (3 and 6 in fig. 7) are set, wherein the solution sample and the solution containing no capture are supplied in a state in which said base plates are fixed on said jig.

As to claim 31, said solution containing no capture is supplied is substantially the same as an area to which said solution sample is supplied, or an area which includes said area to which said solution sample is supplied (), said area having a substantially circular shape (col. 7, lines 46-55 and fig. 3.)

As to claim 32, an area, in which said solution containing no capture is supplied onto said base plate, is considered to have a size which includes two or more areas to each of which said solution sample is supplied (col. 7, lines 46-55 and fig. 3).

As to claim 59, the immobilization solution is an alkyl group (col. 7, line 46.)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 23 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brennan, 5,474,796, in view of Okamoto et al., 6,476,215.

Brennan discloses the invention as claimed (see above). However Brennan does not teach that the chemical reaction is a reaction of amino group and epoxy group (claim 23), nor that the immobilization solution is a solution containing hydrophobic group (claim 25.) Okamoto et al. teach these limitations.

Okamoto et al. teach that an amino group on a solid support and an epoxy group on a nucleic acid can be used to immobilize the nucleic acid to the solid support (col. 6, lines 60-62.) It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the combination of an amino group and epoxy group as taught by Okamoto et al. in the Brennan invention because Okamoto et al. teach that this combination provides the advantage of immobilizing nucleic acids to a solid support. (With respect to claim 25, the epoxy rings are hydrophobic, see col. 13, lines 24-28 and col. 6, lines 60-62.)

3. Claims 12, 13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brennan, 5,474,796, in view of Borrelli et al., 6,350,618.

Brennan discloses the invention substantially as claimed (see above), except for the immobilization solution or the immobilization-reinforcing solution being advanced by mixing the immobilization solution or immobilization-reinforcing solution with the solution sample (claim 12), and the immobilization solution or immobilization-reinforcing solution () and the solution sample () being supplied substantially simultaneously onto said base plate (claim 15). Borrelli et al. disclose this limitation however.

As to claim 12, Borrelli et al. teach that a premixed solution of immobilization solution, i.e., acrylamide monomer solution, is mixed with oligonucleotides and is printed onto substrate functionalized with a silane (col. 11 lines 26-48 and col. 12, lines 6-45.) It would have been obvious to one of ordinary skill in the art at the time the invention was made to print a mixed solution of an immobilization agent and oligonucleotides onto a solid support as taught by Borrelli et al. in the Brennan invention because Borrelli et al. teach that that such a technique provides the advantage of immobilizing the oligonucleotides to a substrate. (As to claim 15, the immobilization agent and the solution sample are considered to be supplied simultaneously onto a solid support because they are mixed in a solution and then applied onto the solid support.)

As to claim 13, Borrelli et al. teach an embodiment wherein beads are in a solution and printed and immobilized onto a substrate and then biomolecules are immobilized onto the beads (col. 16, lines 9 – col. 48.) It would have been obvious to one of ordinary skill in the art at the time the invention was made to print and immobilize beads onto a substrate and then immobilize biomolecules onto the beads as taught by Borrelli et al. in the Brennan invention because Borrelli et al. teach that this method

provides the advantage of performing combinatorial or sequential synthesis (see Borrelli et al., col. 16, lines 47-48.)

4. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brennan, 5,474,796, in view of Hammond et al., 6,255,051.

Brennan discloses the invention substantially as claimed. More specifically, Brennan discloses use of functional groups introduced into the solid support and into the probe to form covalent bonds to more firmly fix the probe to the solid support (col. 7, lines 46-55.) However Brennan does not teach the use of ionic bonds to fix the probe to the solid support.

Hammond et al. teach that, in addition to functional groups providing covalent bonds between nucleic acids and a solid support, ionic interactions can also facilitate immobilization of nucleic acids onto a solid support (col. 18, lines 8-14 and lines 19-20.) Hammond et al. teaches that the binding can be direct as between the nucleic acid and solid support, or indirect such that an intermediate molecule lies between the nucleic acid and the solid support (col. 18, lines 21-23.)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide for ionic bonds between the nucleic acids and the solid support as taught by Hammond et al. in the Brennan device because Hammond et al. teaches that providing for ionic bonds is an alternative to providing for covalent bonds to immobilize nucleic acids onto a solid support.

5. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brennan, 5,474,796, in view of Dattagupta, 4,950,588.

Brennan discloses the invention substantially as claimed. More specifically, Brennan discloses use of functional groups introduced into the solid support and into the probe to form covalent bonds to more firmly fix the probe to the solid support (col. 7, lines 46-55.) However Brennan does not teach that the immobilization solution includes avidin.

Dattagupta teaches that, in addition to functional groups providing covalent bonds between nucleic acids and a solid support, the bonding between the nucleic acid and solid support can be through use of avidin as a linker (col. 18, lines 1-12, and col. 19, line 4.)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use avidin as a linker between the nucleic acids and the solid support as taught by Dattagupta in the Brennan device because Dattagupta teaches that use of avidin as a linker is an alternative to providing for covalent bonds between nucleic acids and a solid support.

6. Claim 58 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brennan, 5,474,796, in view of Balint, Jr. et al., 4,681,870.

Brennan discloses the invention substantially as claimed. More specifically, Brennan discloses use of functional groups introduced into the solid support and into the probe to form covalent bonds to more firmly fix the probe to the solid support (col. 7,

lines 46-55.) However Brennan does not teach that the immobilization solution includes gamma-aminopropyltriethoxysilane. Balint, Jr. et al. however disclose this limitation.

Balint, Jr. et al. teach that gamma-aminopropyltriethoxysilane is used to immobilize proteins to a solid support (col. 3, lines 43-58). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use gamma-aminopropyltriethoxysilane as taught by Balint, Jr. et al. in the Brennan invention because Balint, Jr. et al. teach that gamma-aminopropyltriethoxysilane provides the advantage of immobilizing proteins to a solid support.

7. Claim 60 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brennan, 5,474,796, in view of Sakamoto et al., 6,406,898.

Brennan discloses the invention substantially as claimed (see above). Brennan discloses coupling agents to couple antibodies and nucleic acids, to a solid support (see for example, col. 7, lines 46-55). However, Brennan does not specifically list alginic acid as an example of a coupling agent. Sakamoto et al. disclose this limitation however.

Sakamoto et al. teach that alginic acid is a known immobilization agent (col. 12, line 56 – col. 13, line 5.) It would have been obvious to one of ordinary skill in the art at the time the invention was made to use alginic acid as taught by Sakamoto et al. in the Brennan invention because Sakamoto et al. teach that alginic acid provides the advantage of immobilizing agents.

8. Claim 61 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brennan, 5,474,796, in view of Schwartz, 5,789,261.

Brennan discloses the invention substantially as claimed (see above with respect to claims 7, 11, 14 and 28). Brennan discloses a coupling agent to couple probes such as antibodies and nucleic acids to a solid support (see for example, col. 7, lines 46-55). However, Brennan does not specifically list polyethyleneimine as an example of a coupling agent. Schwartz discloses this limitation however.

Schwartz teaches that polyethyleneimine is a covalent coupling agent for an immunoreagent, such as an antibody, to be immobilized on a styrene solid substrate, such as a well, (col. 4, lines 7-29, col. 5, lines 46-49, col. 8, lines 56-61, col. 10, lines 15-29) Schwartz teaches that when an antibody is covalently attached to a solid surface, the reproducibility of an assay increases because the antibodies are less at risk of being displaced by fibrinogen (col. 4, lines 7-29).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide polyethyleneimine as taught by Schwartz in the Brennan invention in order to covalently attach antibodies to the surface of the wells because Schwartz teaches that covalent attachment of antibodies to the solid surface provides the advantage of increasing reproducibility of an assay by decreasing the risk of antibody displacement by fibrinogen.

9. Claim 62 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brennan, 5,474,796, in view of Wei et al., 6,576,419.

Brennan discloses the invention substantially as claimed (see above with respect to claims 7, 11, 14 and 28). Brennan discloses a coupling agent to couple probes such as antibodies and nucleic acids to a solid support (see for example, col. 7, lines 46-55). However, Brennan does not specifically list polyethylene glycol (PEG) as an example of a coupling agent. Wei et al. discloses this limitation however

Wei et al. teaches that polyethylene glycol can be used to attach oligonucleotides to a solid surface for assay purposes (col. 7, lines 48-57.) It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide polyethylene glycol as the coupling agent in the Brennan invention because Wei et al. teaches that polyethylene glycol provides the advantage of coupling DNA to a solid support.

10. Claim 63 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brennan, 5,474,796, in view of Lopez et al., 5,183,735.

Brennan discloses the invention substantially as claimed (see above with respect to claims 7, 11, 14 and 28). Brennan discloses a coupling agent to couple probes such as antibodies and nucleic acids, to a solid support (see for example, col. 7, lines 46-55). However, Brennan does not specifically list BSA (bovine serum albumin) as an example of a coupling agent. Lopez et al. discloses this limitation however.

Lopez et al. teaches using BSA as a coating on a solid support such as microwells to enhance adherence of DNA to polystyrene wells and to eliminate false

positives due to the binding of anti-histone antibodies, which provides a consistently high level of reproducibility of assays (col. 4, lines 20-43.)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide BSA as the coupling agent in the Brennan invention because Lopez et al. teaches that such a coupling agent provides the advantage of enhancing adherence of DNA to the wells and eliminating false positives, thereby providing high levels of reproducibility of assays, as would be desirable in the Brennan invention.

Response to Arguments

Applicant's arguments with respect to the above rejected claims have been considered but are moot in view of the new ground(s) of rejection. (Applicant's argument that Brennan does not disclose using an ink-jet system to apply a solution containing no capture is persuasive. However, Sluka et al. teach the motivation to supply a solution containing no capture using an ink-jet system, as described above in the rejection.)

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on Mon.-Fri. 10-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ann Lam